IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Luther et al.
Appl. No.	:	10/644047
Filed	:	August 19, 2003
For	:	HARD TIP OVER THE NEEDLE INTRAVENOUS CATHETER
Examiner	:	Daniel L. Robinson
Group Art Unit	:	3742

CERTIFICATE OF MAILING

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

June 4, 2004
(Date)

Vito A. Canuso III, Reg. No. 35,471

DECLARATION OF NICOLAAS C. BESSELING UNDER 37 C.F.R. § 1.132

I, Nicolaas C. Besseling, declare as follows:

1. I have over thirty years experience in the medical device industry, with extensive knowledge and expertise in the diagnostic, treatment, and life support industries. I am a recipient of a BSEE and MSEE from the Technical University of Delft, The Netherlands. I have attached a copy of my curriculum vitae that details my experience. Since 1996 I have been the Principal of BesTech Consulting Services, consulting in the areas of FDA Compliance, Product Safety, Regulatory Affairs, and Product Design. I have provided consulting services on behalf of Applicant in the past.

2. I have studied the above-reference patent application and the particular features of interest regarding the manufacturing of a hard tip one-piece catheter. I have also studied the multi-piece catheter described in U.S. Pat. No. 5,957,893. Based upon my understanding of what is described in both documents, along with a review of the real world difficulties associated with making embodiments of the multi-piece catheter described in the '893, I have the following observations and conclusions that I believe reflect the advancement provided by the inventive features described in the present application.

3. The catheter described in the '893 patent consists of three parts (see Figure 5). The three different parts of the '893 catheter are made of materials with differing properties. As a result, manufacturing of the catheter can be significantly complicated by the different temperatures at which the respective materials can be molded, formed, or joined. The invention of the present application, however, avoids this complication and thereby allows for consistent manufacturing parameters, greatly reducing assembly time.

4. The manufacturing process of the '893 patent requires an annular member (64) to be subject to an RF heating process in a frustoconically shaped cavity mold (68). This process creates an interface of components that is extremely susceptible to the formation of a "bump" at

the location indicated by 50 in Figure 8, namely at the distal end of the catheter body and tip member (58). As a result of this "bump" that will form, there can be increased resistance to insertion into the patient's skin and vascular system causing the patient serious discomfort and rendering the catheter potentially unusable. The one-piece construction of the present invention is not susceptible to the formation of a "bump." As a result, significantly less insertion force is required to penetrate the patient's skin and vascular system, resulting in less trauma and discomfort to the patient.

5. The manufacturing process described in the '893 patent uses RF weldable materials. This process is susceptible to the formation of a "shoulder" at the distal end of the tip member (58) as a result of RF forming, wherein it is extremely difficult to form sharp edges where material is very thin. As a result, there is a pronounced transition from the piercing tip (16) to the tip member (58) by reason of the increased radius of the tip. This requires increased insertion force to penetrate the patient's skin and vascular system and results in serious discomfort, rendering the catheter potentially unusable. In contrast, the manufacturing process of the present invention allows for a much smoother transition from the distal end of the needle (24) to the end of the catheter and can be used with a much wider variety of materials to mold the catheter.

6. The invention described in the present application allows for manufacturing of a hardened distal end of a polyurethane one-piece catheter by treating the distal end to increase the content of high durometer material. For example, the present application describes the methods of imbibing into the catheter tip a relatively hard thermoplastic material that reacts with the existing isocyanate hard segments within the polyurethane catheter and of forming an interpenetrating network polymer in which a polymer of hard thermoplastic material is interweaved with the polymer matrix of the catheter at a molecular level. This avoids the formation of a "bump" and "shoulder", as described above, that results in the manufacturing of the multi-material and multi-part construction and manufacture of the '893 patent. Utilizing non-obvious, one-piece, construction avoids the disadvantages and potential problems associated with the invention of the '893 patent that result from of its multi-material and multi-part construction and manufacture.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are made punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that willful, false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

Dated: 1 June 2004

By: _____
Nicolaas C. Besseling

MRZ-1242